

6111 Broken Sound Parkway NW Boca Raton, FL 33487-3693 (561) 241-9400 Fax (561) 995-5188

March 15, 2000

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204



Dear Sirs:

Notice is hereby given pursuant to Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Rexall, SDV Vitamins, Thompson and Sundown brand names bearing the following statement(s) on the label and/or in the labeling:

E 100 IU, E 200 IU, E 400 IU, E 1000 IU (Sundown): Vitamin E promotes healthy heart and cholesterol function. It is a powerful antioxidant that helps protect cells from free-radical damage. Free radicals can cause cellular destruction which can lead to premature aging. Vitamin E maintains healthy cardiovascular and circulatory function by contributing to normal blood flow.

E 200 IU, E 400 IU, E 1000 IU (Rexall): [It] promotes healthy heart and cholesterol function. Vitamin E is a high-potency antioxidant that helps promote a healthy heart. Vitamin E contributes to healthy skin. Vitamin E helps nutritionally in maintaining cardiovascular function and a healthy circulatory system by contributing to normal blood flow. Vitamin E is an essential vitamin and powerful antioxidant that helps protect cells from free radical damage and enhances the antioxidant activity of Vitamin C and Selenium. Free radicals are unstable molecules that, if left unchecked, can cause cellular destruction which can lead to premature aging.

<u>E 400 IU, E 1000 IU (SDV)</u>: Vitamin E promotes healthy cardiovascular and circulatory systems. Vitamin E is an essential vitamin and powerful antioxidant that helps protect cells from free radical damage and enhances the antioxidant activity of Vitamin C and Selenium. Free radicals are unstable molecules that, if left unchecked, can cause cellular destruction which can lead to premature aging.

<u>E 400 IU (Thompson)</u>: [It] promotes healthy heart and cholesterol function. Vitamin E is an essential vitamin and powerful antioxidant that helps protect cells from free radical damage and enhances the antioxidant activity of Vitamin C and Selenium. Free radicals are unstable molecules that, if left unchecked, can cause cellular destruction which can lead to premature aging.

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The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Vice President of Regulatory Affairs and Assistant General Counsel

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Enclosure